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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GREENE, JAIME M	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
08/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,288	DOGULU ET AL.	
	Examiner	Art Unit	
	Jaime M. Greene	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-25, 29, drawn to a method of detecting predisposition to venous thrombosis.

Group II, claim(s) 26-28, 30-36, drawn to an array.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common technical features are nucleic acid sequences from AT III, protein C, protein S, fibrinogen, factor V, factor II, MTHFR, and ACE. However, these cannot be considered special technical features because AT III, protein C, protein S, fibrinogen, factor V, factor II, MTHFR, and ACE are known in the art. See,e.g., (cited in IDS) Buchholz, et al. AJRI 2003; 50:20-32.

Further restriction requirement

3. The claims are drawn to methods and products which require identifying at least one SNP or mutation in a nucleic acid sample to determine genetic predisposition to VT. The claims are directed to numerous distinct methods recited in the alternative. The language "one or more mutations or polymorphisms" requires that one, two, three or any number up to the total number of SNPs in Table 1 are detected within a sample. For example, a method requiring SNP of Factor V G1691A is distinct from a method requiring SNP of prothrombin G20210A because the methods have a different mode of operation, do not overlap in scope, and they are not obvious variants of one another (see MPEP 806.05(j)). As seen in Table 1, page 70, each of the SNPs are located in genes and sequences.

The claims further encompass many subcombinations which are disclosed as usable together in a single combination and which are also separately usable. For example, consider the following combinations of "one or more" SNPs selected from those disclosed in Table 1:

Subcombination (A): the SNPs or mutations G13268T within AT III, C6216T within Protein C, GAA349AAA within Protein S, α(16)Arg/Cys within Fibrinogen, G1691A within Factor V, G20210A within Factor II, C677T MTHFR, and intron 16 288bp insertion within ACE.

Subcombination (B): the SNPs or mutations C13299T within AT III, G7176A within Protein C, CTA405CCA within Protein S, α(19)Arg/Gly within Fibrinogen, G1628A

within Factor V, G20210A within Factor II, A1298C MTHFR, and intron 16 288bp deletion within ACE.

Combination (A+B): the SNPs or mutations G13268T within AT III, C6216T within Protein C, GAA349AAA within Protein S, α(16)Arg/Cys within Fibrinogen, G1691A within Factor V, G20210A within Factor II, C677T MTHFR, intron 16 288bp insertion within ACE, C13299T within AT III, G7176A within Protein C, CTA405CCA within Protein S, α(19)Arg/Gly within Fibrinogen, G1628A within Factor V, A1298C MTHFR, and intron 16 288bp deletion within ACE.

Each of the combinations of SNPs are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In this case subcombinations (A) and (B) do not overlap in scope and there is no evidence on the record to suggest that they are obvious variants of one another. The subcombinations are separately usable as evidenced by their presentation in the alternative within the claims. Further, subcombination "A" has separate utility such as detecting the SNP, as a marker, or for linkage studies, for examples. So, subcombinations (A) and (B) are distinct. See MPEP § 806.05(d).

These subcombinations are also distinct from the combination which comprises them because the combination does not require the particulars of the subcombination as claimed to show novelty or unobviousness and the subcombinations have utility by themselves or in another combination. The fact that the claim encompasses an

embodiment which relies on only subcombination (B) is evidence that the details of subcombination (A) are not required for patentability of the combination (A+B), and likewise, the fact that the claim encompasses an embodiment which relies on only subcombination (A) is evidence that the details of subcombination (B) are not required for patentability of subcombination (A+B). The fact that the claim encompasses embodiments which use only subcombination (A) or subcombination (B) is evidence that the subcombinations have utility by themselves.

This example particularly discusses only the combinations (A), (B) and (A+B), but the same analysis could be applied to each of the different subcombinations and combinations set forth in the instant claims.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Each SNP must be searched by a separate query of the electronic databases. See MPEP 808.02(C). Therefore, a search for methods which use each SNP or each combination of SNPs is not co-extensive with methods which use each other SNP or each other combination of SNPs , and subsequently, the search and examination for every SNP and every combination of SNP poses an enormous and serious burden on the examiner.

Applicant is required to select a single invention, ie, a single SNP in each of 8 genes or a single combination of SNPs in each of 8 genes required for the claimed

method and for the claimed product. The invention may be a single SNP in each of 8 genes, a combination of more than one SNP from each of 8 genes but less than all of the disclosed SNPs or a combination of all possible claimed SNPs. However, an election of a single invention, ie, a single SNP in each of 8 genes or a single combination of SNPs in each of 8 genes is required. This restriction requirement is predicated on the fact that the methods which use different SNPs or different combinations of SNPs do not appear obvious over one another. Should applicant traverse on the ground that the different SNPS or different combinations of SNPs are not patentably distinct over each other, applicant should submit evident or identify such evidence now of record showing the inventions to be obvious variant over each other or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Applicant is also required to identify which claims read upon the elected invention.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jaime M. Greene whose telephone number is 571-270-

3052. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jaime M. Greene
JMG 8/7/07

JEANINE A. GOLDBERG
PRIMARY EXAMINER
8/13/07